POMERANTZ LLP
Thomas H. Przybylowski
600 Third Avenue, 20th Floor
New York, New York 10016
Telephone: (212) 661-1100
Facsimile: (917) 463-1044
tprzybylowski@pomlaw.com

Attorney for Plaintiff

- additional counsel on signature page -

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ROBERT PATRICK, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. CORMEDIX INC., KHOSO BALUCH, MATTHEW DAVID, and PHOEBE MOUNTS, Defendants.	Case No. CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

Plaintiff Robert Patrick ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters,

based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding CorMedix Inc. ("CorMedix" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired CorMedix securities between July 8, 2020 and May 13, 2021, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. CorMedix is a biopharmaceutical company that focuses on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases in the U.S. and internationally. The Company

is focused on developing its lead product candidate, DefenCath, a purported novel antibacterial and antifungal solution designed to prevent costly and dangerous catheter-related bloodstream infections ("CRBSIs").

3. In July 2020, CorMedix completed submission of a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for DefenCath as a catheter lock solution with an initial indication for use of preventing CRBSIs in patients with end-stage renal disease who are receiving hemodialysis via a central venous catheter.

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) deficiencies existed with respect to DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath; (ii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA for CRBSIs in its present form; (iii) Defendants had downplayed the true scope of the deficiencies with DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

5. On March 1, 2021, CorMedix issued a press release "announc[ing] that the [FDA] cannot approve the [NDA] for DefenCath . . . in its present form." CorMedix informed investors that the "FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility"; that the "FDA did not specify the issues and CorMedix intends to work with the manufacturing facility to develop a plan for resolution when FDA informs the facility of the specific concerns"; that, "[w]hen we are informed of the issues, we will schedule an investor conference call to provide an update on our expected timeline for resolution"; and that, "[a]dditionally, FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications."

6. On this news, CorMedix's stock price fell $5.98 per share, or 39.87%, to close at $9.02 per share on March 1, 2021.

7. Then, on April 14, 2021, Defendants announced that CorMedix would have to take additional steps to meet the FDA's requirements for DefenCath's manufacturing process, including "[a]ddressing FDA's concerns regarding the qualification of the filling operation [that] may necessitate adjustments in the process and generation of additional data on operating parameters for manufacture of DefenCath."

8. On this news, CorMedix's stock price fell $1.44 per share, or 15.37%, to close at $7.93 per share on April 14, 2021.

9. Finally, on May 13, 2021, CorMedix announced that "[b]ased on our analyses, we have concluded that additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA." After an analyst pressed for clearer information on DefenCath's manufacturing deficiencies on a conference call held that same day, Defendant Phoebe Mounts ("Mounts"), CorMedix's Executive Vice President and General Counsel, finally disclosed, *inter alia*, that "there are times when there may be unexpected results obtained"; that the FDA "expect[s] us to generate sufficient data to demonstrate that[the filling] process is a controlled process and is consistent with the agency's requirements for good manufacturing practice"; that "sterility is a very important part of that process," as well as "the accuracy in making sure the right volume of DEFENCATH is loaded into the vials"; that "we are talking about thousands of vials during the manufacturing run"; that Defendant must "generat[e] of a lot of data to make sure that . . . all the equipment has been qualified for the intended use and every step in the manufacturing process has been qualified"; that "th[e] process needs to be very robust, [and] needs to be reproducible"; and that "the burden is on the manufacturer to demonstrate that the facility can do that process reducibly and generate the required product for commercial distribution."

10. On this news, CorMedix's stock price fell $1.51 per share, or 19.97%, to close at $6.05 per share on May 14, 2021.

11. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

12. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

14. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). CorMedix is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

15. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

16. Plaintiff, as set forth in the attached Certification, acquired CorMedix securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

17. Defendant CorMedix is a Delaware corporation with principal executive offices located at 300 Connell Drive, Suite 4200, Berkeley Heights, New Jersey 07922. The Company's common stock trades in an efficient market on the Nasdaq Stock Market ("NASDAQ") under the ticker symbol "CRMD." Prior to February 2, 2021, the Company's common stock traded on the NYSE American ("NYSE") under the same ticker symbol.

18. Defendant Khoso Baluch ("Baluch") has served as CorMedix's Chief Executive Officer at all relevant times.

19. Defendant Matthew David ("David") has served as CorMedix's Chief Financial Officer at all relevant times.

20. Defendant Mounts has served as CorMedix's Executive Vice President and General Counsel at all relevant times.

21. Defendants Baluch, David, and Mounts are sometimes referred to herein as the "Individual Defendants."

22. The Individual Defendants possessed the power and authority to control the contents of CorMedix's SEC filings, press releases, and other market

communications. The Individual Defendants were provided with copies of CorMedix's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with CorMedix, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

23. CorMedix and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

24. CorMedix is a biopharmaceutical company that focuses on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases in the U.S. and internationally. The Company is focused on developing its lead product candidate, DefenCath, a purported novel antibacterial and antifungal solution designed to prevent costly and dangerous CRBSIs.

25. In July 2020, CorMedix completed submission of an NDA to the FDA for DefenCath as a catheter lock solution with an initial indication for use of preventing CRBSIs in patients with end-stage renal disease who are receiving hemodialysis via a central venous catheter.

Materially False and Misleading Statements Issued During the Class Period

26. The Class Period begins on July 8, 2020, when CorMedix issued a press release, during pre-market hours, announcing that it had completed submitting the DefenCath NDA with the FDA for CRBSIs in patients with end-stage renal disease who are receiving hemodialysis via a central venous catheter (the "July 2020 Press Release"). That press release stated, in relevant part, that "all of the modules for the Defencath™ [NDA] have been submitted to the [FDA]"; that "there has been ongoing dialogue with FDA as it reviews the submitted modules"; and that "[t]he NDA contained data from the Company's Phase 3 trial, LOCK-IT-100, in patients undergoing hemodialysis for end-stage renal disease, which showed a 71% reduction in CRBSIs relative to the heparin control arm . . . with a good safety profile."

27. The July 2020 Press Release also quoted Defendant Baluch, who represented, in relevant part, that CorMedix was "very pleased to have completed the submission of the NDA, despite the limitations imposed by the COVID-19 pandemic, which delayed some required laboratory testing and our submission[,]"

and that "[s]ubmission of our first NDA is an important milestone for CorMedix and is a significant accomplishment by the Company."

28. On August 10, 2020, CorMedix issued a press release reporting the Company's results for the second fiscal quarter of 2020 and providing a business update (the "2Q20 Press Release"). That press release represented, *inter alia*, that CorMedix had "[c]ompleted the rolling submission and review of the [NDA] for Defencath to the FDA for the prevention of . . . CRBSIs[] in patients undergoing hemodialysis via catheter[,]" and that Defendants "[c]ontinued to expand our efforts to prepare for the commercial launch of Defencath."

29. The 2Q20 Press Release also asserted that CorMedix had invested significant funds into Defencath's research and development ("R&D"), thereby indicating to investors that Defencath's manufacturing was well-supported. Specifically, the 2Q20 Press Release stated, in relevant part, that CorMedix recognized a "higher net loss . . . in 2020 compared with 2019 . . . due to increased expenses related to our preparations for Defencath's commercial launch[,]" that "[w]e recorded significant increases in . . . R&D[,]" and that "R&D expense increased approximately 91% to $5.7 million from $3.0 million, mainly due to a $3.4 million purchase of raw material that will be used in the production of Defencath for sale in the U.S. upon receipt of FDA marketing approval[.]"

30. Additionally, the 2Q20 Press Release quoted Defendant Baluch, who stated, in relevant part, that "[w]e have made significant progress on our goal of bringing Defencath to the U.S. market as a catheter lock solution for hemodialysis"; that "[w]e also are making necessary preparations for the launch of Defencath in the U.S. hemodialysis market, following FDA approval"; and that "[w]e believe we have the team, the focus, and a therapy that will meaningfully improve patient outcomes and are excited about the opportunities in front of us."

31. That same day, CorMedix filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2020 (the "2Q20 10-Q"). The 2Q20 10-Q discussed the Company's DefenCath NDA submission with the FDA, stating, *inter alia*, that "[i]n March 2020, the Company began the modular submission process for the NDA for Defencath for the prevention of CRBSI in hemodialysis patients, and recently announced on July 8, 2020, that submission of all modules for the NDA was completed"; that "[t]he Company requested Priority Review of the NDA, which if granted, would provide for a goal for the FDA of a six-month review period, instead of ten months for applications under standard review"; and that "[t]he Company has not been informed of any delays by the FDA in the review of the NDA[.]"

32. Appended as exhibits to the 2Q20 10-Q were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein Defendants Baluch

and David certified that "[t]he [2Q20 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act], as amended[,]" and that "[t]he information contained in the [2Q20 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

33. On August 31, 2020, CorMedix issued a press release announcing the FDA's acceptance for filing and priority review of the DefenCath NDA for CRBSIs (the "August 2020 Press Release"). That press release stated that the FDA "noted that it is planning to hold an advisory committee meeting to discuss the [NDA] application and that it had not identified any potential review issues at this time."

34. The August 2020 Press Release also quoted Defendant Baluch, who represented that "[t]he NDA acceptance is truly a momentous achievement for CorMedix, the internal and external teams involved with the submission, and most importantly, the hemodialysis patient community[,]" and that Defendants "are proud of our team for exceptional effort to get us to this point and look forward to bringing Defencath to patients to prevent the serious complications and costs associated with CRBSI in this significant patient population."

35. Additionally, the August 2020 Press Release quoted Defendant Mounts, who asserted, in relevant part, that "the FDA's acceptance of our first NDA as an essential step toward our goal of offering Defencath in the U.S. as the first antimicrobial catheter lock solution for the prevention of life-threatening CRBSI in

hemodialysis patients[,]" that "[w]e are very appreciative that the [FDA] granted priority review and despite the ongoing pandemic," and that "we look forward to continuing to work together [with the FDA] expeditiously to complete the review of the Defencath NDA to address an unmet medical need."

36. On November 5, 2020, CorMedix issued a press release reporting the Company's results for the third fiscal quarter of 2020 and providing a business update (the "3Q20 Press Release"). That press release represented, in relevant part, that "CorMedix continues its interactions with the FDA regarding the . . . NDA[] for Defencath™ for the prevention of . . . CRBSIs[] in patients undergoing hemodialysis via central venous catheter[,]" and that "CorMedix has continued to expand its efforts to prepare for the commercial launch of Defencath[,]" including interactions with certain market participants, that "have been positive and clearly position CorMedix to ensure that, once Defencath is approved by the FDA, it will be in the best possible position to successfully launch in the US market."

37. The 3Q20 Press Release also continued to assert that CorMedix had invested significant funds into Defencath's R&D, thereby indicating to investors that Defencath's manufacturing was well-supported. Specifically, the 3Q20 Press Release stated, in relevant part, that "[o]perating expenses during the third quarter of 2020 . . . increase[d] . . . approximately 28%[,]" which "was due [in part] to a $0.4 million, or 16%, increase in R&D expense"; that "[o]perating expenses during the

nine-month period ended September 30, 2020 . . . increase[d] . . . 36%, due [in part] to a 32% increase in R&D expense"; and that "R&D expense for the first nine months of 2020 included approximately $3.8 million in costs related to the purchase of raw materials and manufacturing of Defencath prior to its potential marketing approval and also included increased staffing costs."

38. Additionally, the 3Q20 Press Release quoted Defendant Baluch, who stated, in relevant part, that "[w]e have continued to make progress on our goal of bringing Defencath to the U.S. market as a catheter lock solution for hemodialysis"; that "[w]e look forward to discussing Defencath with the Antimicrobial Drugs Advisory Committee in January, ahead of the February 28, 2021 PDUFA date for the product"; that "[w]e also are making necessary preparations for the launch of Defencath in the U.S. hemodialysis market, following FDA approval"; and that "[w]e believe we have the team, the focus, the resources, and a novel catheter lock solution that will meaningfully improve patient outcomes and are excited about the opportunities in front of us."

39. That same day, CorMedix filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended September 30, 2020 (the "3Q20 10-Q"). The 3Q20 10-Q contained substantively the same statements as referenced in ¶ 28, *supra*, discussing the submission process for the DefenCath NDA while also advising, *inter alia*, that

"[t]he FDA noted that it is planning to hold an advisory committee meeting to discuss the application and that it had not identified any potential review issues at this time[,]" and that "[t]he Company has not been informed of any delays by the FDA in the review of the NDA, but . . . pre-approval inspections are required for manufacturing sites."

40. Appended as exhibits to the 3Q20 10-Q were substantively the same SOX certifications as referenced in ¶ 32, *supra*, signed by Defendants Baluch and David.

41. On November 18, 2020, CorMedix issued a press release announcing the FDA's decision that an advisory committee meeting for the DefenCath NDA for CRBSIs was not needed (the "November 2020 Press Release"). That press release advised that the FDA "noted that it was planning to hold an advisory committee meeting to discuss the application for Defencath to be used as a catheter lock solution in hemodialysis patients for the prevention of [CRBSI] and that it had not identified any potential review issues at that time[,]" and that "CorMedix has been notified that based on the [FDA]'s ongoing dialogue with the Company, discussion at an advisory committee is not needed, and it will continue to work on the application with CorMedix during the remainder of the review cycle."

42. The November 2020 Press Release also quoted Defendant Baluch, who asserted that CorMedix and the FDA were working closely together on the

DefenCath NDA for CRBSIs, stating that "[w]e are very happy with the level of engagement between FDA and the CorMedix team during the NDA review process[,]" and that "[w]e look forward to completion of the review of the NDA and are considering all strategic options to be able to successfully bring Defencath to the U.S. market as soon as possible."

43. Additionally, the November 2020 press Release quoted Defendant Mounts, who likewise asserted that CorMedix and the FDA were working closely together on the DefenCath NDA for CRBSIs, stating that "[i]t is gratifying that the tremendous effort of the CorMedix team has resulted in continuing progress with the FDA in the review of the NDA and that the decision was made that no discussion with an advisory committee is needed[,]" and that "[w]e intend to continue our effort and dialogue with the [FDA] to ensure that the priority review process can be completed expeditiously to address the unmet medical need of hemodialysis patients for an antimicrobial catheter lock solution to prevent life-threatening CRBSI."

44. The statements referenced in ¶¶ 26-43 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) deficiencies existed with respect to DefenCath's manufacturing process and/or at the facility responsible for

manufacturing DefenCath; (ii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA for CRBSIs in its present form; (iii) Defendants had downplayed the true scope of the deficiencies regarding DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

45. On March 1, 2021, CorMedix issued a press release "announc[ing] that the [FDA] cannot approve the [NDA] for DefenCath . . . in its present form." Specifically, CorMedix informed investors that the FDA had noted concerns regarding DefenCath's manufacturing, stating, in relevant part:

> [T]he [FDA] cannot approve the [NDA] for DefenCath . . . in its present form. FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility. FDA did not specify the issues and CorMedix intends to work with the manufacturing facility to develop a plan for resolution when FDA informs the facility of the specific concerns. When we are informed of the issues, we will schedule an investor conference call to provide an update on our expected timeline for resolution. Additionally, FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications . . . .
>
> Satisfactory resolution of these issues is required for approval of the DefenCath NDA by a pre-approval inspection and/or adequate manufacturing facility responses addressing these concerns. If an inspection is required, the FDA is currently facing a backlog due to the

> pandemic and are actively working to define an approach for scheduling outstanding inspections once safe travel may resume . . . .

46. On this news, CorMedix's stock price fell $5.98 per share, or 39.87%, to close at $9.02 per share on March 1, 2021. Despite this decline in the Company's stock price, CorMedix securities continued to trade at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misrepresentations and omissions regarding the true scope of the deficiencies with respect to DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath.

47. For example, on March 30, 2021, CorMedix issued a press release reporting the Company's results for the fourth fiscal quarter and full year of 2020, and providing a business update. That press release continued to generally advise that the "FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility, and has requested a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from vials."

48. That same day, Defendants hosted a conference call with investors and analysts to discuss, among other things, the regulatory pathway for the DefenCath NDA for CRBSIs. On that call, Defendant Mounts advised:

> The timeline we outlined on March 1 and reiterated on March 9 for a planned meeting with the FDA in mid-April remains on track based on the progress we have made. We have been working intensely with our

> third-party manufacturing facility to develop the proposed resolutions to the deficiencies.
>
> There has been a strong collaborative effort to develop responses for each of the six deficiencies identified by FDA for the manufacturing facility. In addition, we have developed the protocol for the manual extraction study being required by FDA to demonstrate that the labeled volume of the drug product can be consistently withdrawn from vials.
>
> I am pleased to announce that FDA has granted our request to meet with them to begin resolving the outstanding deficiencies. As we have previously stated, the purpose of the meeting with FDA is to obtain agreement with the agency on the adequacy of our proposed plans for resolution of the deficiencies. Our contract manufacturing organization will join us in the meeting with FDA.
>
> As we planned, the meeting will occur in mid-April, and we will provide an update on our progress and timeline for resolution of the deficiencies after the meeting with FDA. Our goal is to ensure that FDA can conclude that the manufacturing facility is ready to support commercial operation for DEFENCATH without the need for an on-site inspection.
>
> As I have explained on previous calls, FDA identified the deficiencies based on a review of records that it had requested from the [contract manufacturing organization ("CMO")].

49. On the same call, regarding Defendant's anticipated meeting with the FDA to discuss the DefenCath NDA, a JMP Securities analyst asked whether "you will actually have any of the work requested by FDA completed by the meeting, either in terms of documentation protocols, or the vial fill volume study or airflow visualization studies that they asked for," and whether "you've actually completed any, or have any new data to take to the meeting?" In response, Defendant Mounts assured investors, "yes, we obviously were involved in developing the proposed

responses"; that "[s]ome of those proposed responses involve existing documentation"; that "we make sure that we -- where we could, we provided information that was responsive to the deficiency"; and that "there is new information there for them to review for some of the responses."

50. The JMP Securities analyst followed up by noting "[y]ou mentioned that there was a couple of questions related to equipment that was not relevant to DEFENCATH" and asked "[i]s it still your view that those parts of the CRL are for equipment not relevant to DEFENCATH?" In response, Defendant Mounts stated: "Maybe, yes. Yes, Jason, the issue was planned expansion at the manufacturing facility, which involved installation of new equipment. That is new equipment non-intended for manufacturer of DEFENCATH. So, the information that has been used and is in place is the appropriate equipment for DEFENCATH manufacture."

51. On the same call, a Truist Securities analyst observed: "[T]he impression is that it was the[CMO's] deficiencies, so what are you -- why do you need to be involved in addressing their issues? What is it that you can contribute to the CMO's deficiencies?" In response, Defendant Mounts advised:

> I think folks don't understand that there's a parallel process here. As you noted, we have direct control over documentation and information on manufacturing, that's submitted directly to the new drug application. As part of that process, FDA inspects the manufacturing facility and reviews documentation and the facility for its ability to manufacture that product in a commercial setting.

> So the inspection by FDA, whether it's by records assessment or an on-site inspection, involves reviewing manufacturing records for the product in the NDA, but it also goes broader than that. It goes to the actual facility and the equipment to the maintenance and the training and the personnel.
>
> So, it's a parallel process, but obviously they are intertwined and can't be separated, because FDA is there to look at the potential for that facility to manufacture the product that's the subject of the NDA.

52. Also on March 30, 2021, CorMedix filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2020 (the "2020 10-K"). The 2020 10-K advised, *inter alia*:

> As we announced in March 2021, the FDA has informed us that it will not approve the NDA for DefenCath in its present form. The FDA noted concerns at the third-party manufacturing facility after a review of records requested by the FDA and provided by the manufacturing facility. We are working with the manufacturing facility to develop plans for resolution of the deficiencies. Additionally, the FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications. We expect to be able to complete this requirement expeditiously. Satisfactory resolution of these issues is required for approval of the DefenCath NDA by a pre-approval inspection and/or adequate manufacturing facility responses addressing these concerns.

53. With respect to CorMedix's CMOs, the 2020 10-K assured investors, in relevant part, that Defendants "are confident that [our] CMO's [for DefenCath] have adequate capacity to produce the volumes needed, [and] that there exists a

sufficient number of potential alternate sources for the drug substances required to produce our products, as well as third-party manufacturers[.]"

54. Appended as exhibits to the 2020 10-K were substantively the same SOX certifications as referenced in ¶ 32, *supra*, signed by Defendants Baluch and David.

55. The statements referenced in ¶¶ 47-54 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Defendants had downplayed the true scope of the deficiencies regarding DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath; and (ii) as a result, the Company's public statements were materially false and misleading at all relevant times.

56. On April 14, 2021, pre-market, CorMedix issued a press release announcing "that it has met with the [FDA] to discuss proposed resolutions for the deficiencies identified in the [CRL] to CorMedix and the Post-Application Action Letter received by the third-party manufacturer (CMO) from FDA for the [NDA] for DefenCath" (the "April 2021 Press Release"). Specifically, that press release disclosed that CorMedix would have to take additional steps to meet the FDA's requirements for DefenCath's manufacturing process, stating, in relevant part:

> Addressing FDA's concerns regarding the qualification of the filling operation may necessitate adjustments in the process and generation of additional data on operating parameters for manufacture of DefenCath. CorMedix and the CMO are currently evaluating available data to determine if additional process qualification will be needed with subsequent validation to address these issues.
>
> The FDA stated that the review timeline would be determined when the NDA resubmission is received and that it expected all corrections to facility deficiencies to be complete at the time of resubmission so that all corrective actions may be verified during an on-site evaluation in the next review cycle, if the FDA determines it will do an onsite evaluation.

57. On this news, CorMedix's stock price fell $1.44 per share, or 15.37%, to close at $7.93 per share on April 14, 2021. Despite this decline in the Company's stock price, CorMedix securities continued to trade at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misrepresentations and omissions regarding the true scope of the deficiencies with respect to DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath.

58. For example, the April 2021 Press Release assured investors that "[r]epresentatives from both CorMedix and the CMO participated in the meeting with FDA to ensure that there is alignment on addressing the [FDA]'s concerns[,]" that "[t]here is now an agreed upon protocol for the manual extraction study identified in the CRL that FDA is requiring as confirmation of in-process controls to demonstrate that the labeled volume can be consistently withdrawn from the vials[,]" that "CorMedix expects to be able to complete this requirement in the next

several weeks[,]" and that "CorMedix will provide updates on the timeline as resolution of the deficiencies proceeds."

59. The statements referenced in ¶ 58 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Defendants had downplayed the true scope of the deficiencies regarding DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath; and (ii) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Fully Emerges

60. On May 13, 2021, post-market, CorMedix issued a press release reporting the Company's results for the first fiscal quarter of 2021 and providing a business update. That press release disclosed, in relevant part, that "[b]ased on our analyses, we have concluded that additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA."

61. That same day, also post-market, Defendants hosted a conference call with investors and analysts to discuss, among other things, the regulatory pathway for the DefenCath NDA for CRBSIs. On that call, Defendant Mounts stated in her opening remarks, *inter alia*:

> As we have explained previously, the major focus of FDA's concerns was on the qualification of the filling operation and CorMedix and the CMO have been evaluating available data to assess the need for adjustments in the manufacturing process and generation of additional data on operating parameters for manufacture of DEFENCATH.
>
> Based on our analysis, we have concluded that additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA. As a result, our current plan is to be able to resubmit the defend cap NDA in the fourth quarter of 2021.

62. Dissatisfied with Defendants' continued ambiguous and general descriptions of the deficiencies identified with DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath, a Needham & Company analyst pressed Defendants for clearer details on the deficiencies and the Company's steps to address them, stating, in relevant part:

> I and probably most other people on this call and investors [are not] necessarily regulatory experts for which I apologize for any deficiency in my own notes and trying to interpret things, ***but I can't imagine I'm alone in not being able to follow some of the details you guys have given. So I'm just hoping maybe with a little bit of extra breadth and maybe walk me through it***, I ignored on these things, although I got to I have sapped through a bunch of these.
>
> When you say you have additional qualification processes that need to address the FDA, and you think you can submit in the fourth quarter an NDA. And then later on, you were talking about some manufacturing, validation that you need beforehand as much as you can. And I get it. These are not easy questions, and there is a lot of uncertainties to deal with the FDA. But can you maybe timeline me through or just slowly, treat me like I'm not all that smart . . . . What the steps are that you think you need to achieve by this 4Q NDA submission?

(Emphasis added.)

63. Specifically pressed for more details and a clearer picture of the regulatory hurdles currently facing CorMedix's manufacturing for DefenCath, Defendant Mounts finally disclosed, in relevant part:

> [I]t is a complicated process and that it is not simple, and like all technical work, needs to be conducted with precision and is subject to issues when something can go wrong. It is highly sophisticated equipment. And so there are times when there may be unexpected results obtained.
>
> FDA's concern as they express to us during our meetings with them focused on the filling operation, which is the process by which DEFENCATH is during a sterile procedure loaded into the vials and then the vials are kept.
>
> They expect us to generate sufficient data to demonstrate that, that process is a controlled process and is consistent with the agency's requirements for good manufacturing practice. So clearly, sterility is a very important part of that process, but also the accuracy in making sure the right volume of DEFENCATH is loaded into the vials. And we are talking about thousands of vials during the manufacturing run.
>
> So as I said, it is a complicated process and technically very involved and involves a generation of a lot of data to make sure that the process itself is using the jargon qualified, which means all the equipment has been qualified for the intended use and every step in the manufacturing process has been qualified.
>
> And that everything works as it is intended to produce the product that has to meet its specifications. So they are very detailed requirements on a chemical basis as well on a performance basis that is required for the product.
>
> And so that process needs to be very robust, needs to be reproducible. And the burden is on the manufacturer to demonstrate that the facility can do that process reducibly and generate the required product for commercial distribution.

64. On this news, CorMedix's stock price fell $1.51 per share, or 19.97%, to close at $6.05 per share on May 14, 2021.

65. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

66. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired CorMedix securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

67. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, CorMedix securities were actively traded on the NASDAQ and NYSE. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified

from records maintained by CorMedix or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

68. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

69. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

70. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of CorMedix;
- whether the Individual Defendants caused CorMedix to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of CorMedix securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

71. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

72. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- CorMedix securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ and NYSE and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold CorMedix securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

73. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

74. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

75. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

76. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

77. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a

fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of CorMedix securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire CorMedix securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

78. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for CorMedix securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about CorMedix's finances and business prospects.

79. By virtue of their positions at CorMedix, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

80. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of CorMedix, the Individual Defendants had knowledge of the details of CorMedix's internal affairs.

81. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of CorMedix. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to CorMedix's businesses, operations, future

financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of CorMedix securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning CorMedix's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired CorMedix securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

82. During the Class Period, CorMedix securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of CorMedix securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of CorMedix securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The

market price of CorMedix securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

83. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

84. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

85. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

86. During the Class Period, the Individual Defendants participated in the operation and management of CorMedix, and conducted and participated, directly and indirectly, in the conduct of CorMedix's business affairs. Because of their senior positions, they knew the adverse non-public information about CorMedix's misstatement of income and expenses and false financial statements.

87. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to CorMedix's financial condition and results of operations, and to correct promptly any public statements issued by CorMedix which had become materially false or misleading.

88. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which CorMedix disseminated in the marketplace during the Class Period concerning CorMedix's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause CorMedix to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of CorMedix within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of CorMedix securities.

89. Each of the Individual Defendants, therefore, acted as a controlling person of CorMedix. By reason of their senior management positions and/or being directors of CorMedix, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, CorMedix to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised

control over the general operations of CorMedix and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

90. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by CorMedix.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: July 22, 2021

Respectfully submitted,

POMERANTZ LLP

/s/ Thomas H. Przybylowski
Thomas H. Przybylowski
Jeremy A. Lieberman*
J. Alexander Hood II*
600 Third Avenue, 20th Floor
New York, New York 10016
Telephone: (212) 661-1100
Facsimile: (212) 661-8665
tprzybylowski@pomlaw.com
jalieberman@pomlaw.com
ahood@pomlaw.com

BRONSTEIN, GEWIRTZ &
GROSSMAN, LLC
Peretz Bronstein*
60 East 42nd Street, Suite 4600
New York, New York 10165
Telephone: (212) 697-6484
Facsimile: (212) 697-7296
peretz@bgandg.com

(**pro hac vice* applications forthcoming)

Attorneys for Plaintiff